DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 16, 2015

Spine Wave, Incorporated
Ms. Roaida Johnson
Senior Regulatory Affairs Manager
3 Enterprise Drive, Suite 210
Shelton, Connecticut 06484

Re: K142980
Trade/Device Name: Proficient™ Facet Screw Spine System
Regulatory Class: Unclassified
Product Code: MRW
Dated: December 30, 2014
Received: December 31, 2014

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142980

Device Name
Proficient™ Facet Screw Spine System

Indications for Use *(Describe)*

The Proficient™ Facet Screw Spine System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from C2 to S1. The Proficient™ Facet Screw Spine System is intended for transfacet fixation, in which the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. The Proficient™ Facet Screw Spine System is indicated for treatment of any or all of the following:

- Pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity
- Spondylolisthesis
- Spondylolysis
- Degenerative Disc Disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies
- Degeneration of the facets with instability
- Trauma including spinal fractures and/or dislocations

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary
Proficient™ Facet Screw Spine System

1. Submitter Information

Submitter:	Spine Wave, Inc.
Address:	Three Enterprise Drive Suite 210 Shelton, CT 06484
Telephone:	203-712-1839
Telefax:	203-944-9493
Contact:	Roaida R. Johnson
Date Prepared:	December 30, 2014

2. Device Information

Trade Name:	Proficient™ Facet Screw Spine System
Common Name:	Facet Screw Spinal System
Classification:	Unclassified
Product Code:	MRW

3. Purpose of Submission

The purpose of this submission is to gain clearance for a new facet screw system.

4. Predicate Device Information

The Proficient™ Facet Screw Spine System described in this submission is substantially equivalent to the following predicates:

Primary Predicate Device	**Manufacturer**	**510(k) Number**
TranS1® Facet Screws	Trans1®	K073515

Additional Predicate Devices	**Manufacturer**	**510(k) Number**
Venus Facet Screw System	Apollo Spine	K120340
CS Facet Compression Device	Triage Medical, Inc	K052043

5. Device Description

The Proficient™ Facet Screw Spine System consists of a selection of non-sterile, single use screws manufactured from titanium alloy conforming to ASTM F136. The screws are provided in multiple diameters and various lengths to accommodate variations in patient anatomy.

6. Indications for Use

The Proficient™ Facet Screw Spine System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from C2 to S1. The Proficient™ Facet Screw Spine System is intended for transfacet fixation, in which the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. The Proficient™ Facet Screw Spine System is indicated for treatment of any or all of the following:

- Pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity
- Spondylolisthesis
- Spondylolysis
- Degenerative Disc Disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies
- Degeneration of the facets with instability
- Trauma including spinal fractures and/or dislocations

7. Comparison of Technological Characteristics

The substantial equivalence of the Proficient™ Facet Screw Spine System to the predicates is shown by similarity in intended use, indications for use, materials and performance.

8. Performance Data

The following tests were performed to demonstrate the substantial equivalence of the Proficient™ Facet Screw Spine System to its predicate:

- Static and dynamic three-point bending (ASTM F1264)
- Axial pullout (ASTM F543)
- Torque to failure (ASTM F543)

9. Conclusion

Based on the indications for use, technological characteristics, performance testing and comparison to the predicates, the Proficient™ Facet Screw Spine System has been shown to be substantially equivalent to the predicate devices identified in this submission, and does not present any new issues of safety or effectiveness.